

Application Serial No.: 10/099,822
Amdt. dated September 20, 2005
Reply to Office Action of June 20, 2005

REMARKS/ARGUMENTS

The Office Action dated June 20, 2005 and the references cited therein have been carefully considered. In response to the Office Action, Applicant has amended the Abstract and Claims 16, 21, 25 and 29 which, when considered with the remarks set forth below, are deemed to place the case in condition for allowance. As a result of the present Amendment, Claims 16-32 remain in the case for continued prosecution.

In the Office Action, Claims 16-32 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and Claims 16-24 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. More specifically, the Examiner states that the limitation relating to the feedback from clinical signals from “at least one other organ of the patient,” for controlling the blood pump and the pacemaker, is not described in the specification. The Examiner states that there is no specific guidance given in the specification as to which organ signals are relevant to the adjustment of the pump or the pacemaker. The Examiner further states that the specification fails to teach a single monitor capable of detecting both clinical signals from the heart and from other organs as currently claimed.

Also in the Office Action, the amendment filed 5/6/05 has been objected to under 35 U.S.C. § 132(a) as introducing new matter into the disclosure. In particular, the Examiner states that a single monitor that is capable of detecting both clinical signals from the heart and from other organs is added material which is not supported by the original disclosure.

Further in the Office Action, the Abstract of the disclosure has been objected to because of the use of “means” language. The Examiner requires correction of the Abstract.

Claims 16-20, 22-28 and 30-32 have also been rejected under 35U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,722,930 to Larson, Jr. et al. in view of U.S. Patent

No. 5,318,592 to Schaldach. Specifically, the Examiner states that the Larson patent discloses the invention substantially as claimed, but does not disclose the use of clinical signal monitoring from other organs as feedback for control of the ventricular assist device.

In response to the §112 rejections to the claims and §132(a) objection to the previous amendment, Applicant has amended independent Claim 16 to define an attachment for measuring a clinical signal from at least one other organ of the patient separate from the monitor which measures clinical signals from the heart. Support for “a set of attachments for measuring biological and or clinical signals at various organs both inside and outside the patient’s body” is found in the first full paragraph of page 2 of the specification. Thus, Claim 16 no longer recites a single monitor for measuring clinical signals from the heart and from other organs. Independent Claim 25 has been amended to recite the step of sending the clinical signals from the heart to the control means.

It is believed that these amendments to Claims 16 and 25 satisfy the written description and definiteness requirements of §112 and further overcome the §132 objection to the prior amendment. With respect to the written description requirement, the Examiner states that a particular feedback system utilizing the detected organ signals would necessarily be required for proper system control. Independent Claim 16, as amended, now defines a monitor for measuring clinical signals from the heart, a separate attachment for measuring clinical signals from at least one other organ and a control means including an input means for entering a command. It is respectfully submitted that Claim 16, as amended, does not require the description of a particular feedback system for proper pump control.

In particular, it is within the scope of Claim 16 that the command entered into the input means of the control means is one entered by a physician based at least in part on the clinical signals from another organ measured by the attachment. The control means controls the linear flow blood pump and the pacemaker based on this entered command and on the clinical signals from the heart measured by the monitor. In other words, the clinical signals measured from another organ are not fed back directly to the control means, but instead are first interpreted by the physician who may or may not enter a command into the control

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means based on the physician's diagnosis. Thus, the "feedback" function for controlling the blood pump and pacemaker, based on clinical signals from another organ, is performed by the physician.

Additionally, while the control means further controls the blood pump and pacemaker based on clinical signals from the monitor, these signals are measured from the heart. Use of these signals for controlling the blood pump and the pacemaker are described in the first five paragraphs on page 5 of the specification. Moreover, it is a simple matter for one skilled in the art to envision a blood pump and/or pacemaker feedback control system based on measured clinical signals from the heart, such as heart rate, or blood flow volume, as described in the specification. Thus, it is respectfully submitted that Claim 16, as amended, satisfies the written description requirement of 35 U.S.C. §112.

With respect to method Claim 25, here too the steps of controlling the blood pump and the pacemaker are based on an entered command and the measured clinical signals from the heart. In other words, the clinical signals from another organ are not sent directly to the control means, but again may be first interpreted by a physician who may in turn enter a feedback command into the control means based on his analysis. Thus, the feedback system for utilizing the clinical signals from another organ may simply be the physician. Therefore, it is respectfully submitted that Claim 25, as amended, satisfies the written description requirement of 35 U.S.C. §112.

Turning to the indefiniteness rejection under §112 and the objection under §132, as mentioned above, independent Claims 16 and 25 have been amended to make clear that there are separate means for measuring the clinical signals from the heart and for measuring the clinical signals from the at least one other organ. In other words, the claims no longer define a single monitor for measuring both types of clinical signals. Accordingly, it is respectfully submitted that these rejections and objections have been overcome.

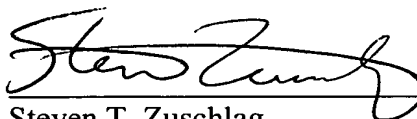
In response to the prior art rejections, Applicant has further amended independent Claim 16 to define an attachment including a magnetic induction means for measuring a clinical signal from at least one other organ of the patient across the skin of the patient.

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Applicant has further amended independent method Claim 25 to recite the step of measuring a clinical signal from at least one other organ across the skin of the living being with a magnetic induction means. It is respectfully submitted that neither the Larson nor the Schaldach patent, taken alone or combined, teaches or suggests an attachment including a magnetic induction means for measuring a clinical signal from at least one other organ of the patient across the skin of the patient. Accordingly, it is respectfully submitted that independent Claims 16 and 25, and the claims that depend therefrom, patentably distinguish over the prior art.

In view of the foregoing amendment and remarks, favorable consideration and allowance of the application with new Claims 16-32 are respectfully solicited. If the Examiner believes that a telephone interview would assist in moving the application toward allowance, he is respectfully invited to contact the Applicant's attorney at the telephone number listed below.

Respectfully submitted,



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